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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/533,399 | 03/22/2000 | Maria Gabriella Santoro | 10167-004-999 | 9404 |

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NEW YORK, NY 100362711

EXAMINER

TRAVERS, RUSSELL S

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 07/01/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/533,399

Applicant(s)

Santoro et al

Examiner

R.S. Travers J.D., Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-56 is/are pending in the application.
- 4a) Of the above, claim(s) 41-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-40 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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The amendment filed May 1, 2003 has been received and entered into the file.

Applicant's arguments filed May 1, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 36-57 are presented for examination.

Claims 41-53 are directed to method for treating viral infections that is independent or distinct from the invention originally claimed for the following reasons: the original election was to cyto-protective uses, not disease therapy.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, subject matter in claims 41-53 not reading on the elected subject matter is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 36-37 and 54-55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals & Interferences in *Ex parte Wu*, 10 USPQ2d 2300 (BdApls 1989) at 2303, as to where

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broad language is followed by "such as" and then narrow language. The Board stated, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. In the present instance, claims 36 and 37 recite the broad recitation of side chain at position 4 or 5, and the claim also recites, lacks an aliphatic side chain at position 4 or 5 not containing the aliphatic chain, which is a narrower statement of the range/limitation. Applicants recitation of the broad range or limitation together with a narrow range or limitation renders independent claims 36 and 37, and dependant claims 54 and 55 properly rejected as indefinite.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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Claims 36-40 and 54-56 are rejected under 35 U.S.C. § 103 as being unpatentable over Amici et al, Noyori et al and Del Soldato, newly cited, or of record.

Amici et al, Noyori et al and Del Soldato teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for providing cyto-protection, viewed by the skilled artisan as indistinguishable from those uses herein claimed.

Claims 36-40 and 54-56, and the primary references, differ as to:

- 1) the recitation of proposed biochemical action mediating the therapy,
- 2) recitation of patients possessing numerous diseases, and
- 3) recitation of specific compounds.

The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing

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novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Attention is directed to the instant claims reading on a cyto-protective utility. The skilled artisan would treat patients requiring cyto-protection, with cyto-protective agents, regardless the absence, or presence of additional etiological agents, or maladies. Claims 36-40 and 54-56 read on a cyto-protective utility, not another unrelated therapeutic regimen. Individuals requiring cyto-proactive therapy may be vexed by numerous maladies unrelated to their required cyto-protective needs. Applicant should take care to maintain distance from other unrelated utilities.

The skilled artisan, possessing a compound for a therapeutic use possesses that compound's homologs, analogs, isomers and bioisosteres; to include all salts, acids and esters. In the instant case, the claimed compounds are old and well known therapeutic agents, rendering pharmaceutical compositions containing these old therapeutic agents obvious.

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RESPONSE TO ARGUMENTS

Examiner notes Noyori et al teach the heat shock protein induction providing cytoprotective benefits employing methyl substituted cyclopentane ring structures. The skilled artisan would not view methyl substitution as an "aliphatic side chain".

Additionally, Rossi et al teach a monosubstituted cyclopentane ring structure as inducing heat shock protein 70 (HSP70) and thereby providing the cytoprotective benefit herein envisioned.

If mono substitution is envisioned for the instant claims, Examiner suggests employing the verbiage "has one aliphatic side chain for both positions 4 and 5 wherein the aliphatic side chain is either at position 4 or position 5".

Applicants' rebuttal arguments have been fully considered and are view as unconvincing. Amici et al teach the claimed prostaglandin as old, well know, cyto-protective and inducing heat shock protein. The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in

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the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 102.

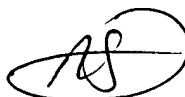
Applicant's arguments regarding the long chain aliphatic are not convincing. Noyori et al teach various 5 carbon ring compounds possessing C₁-C₁₂ aliphatic substituents as possessing cyto-protective properties. Possessing these teachings, the skilled artisan would have been motivated to employ these compounds for the use herein claimed and enjoy a reasonable expectation of therapeutic success. As stated above, arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that

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the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
Art Unit 1617